

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE
in its capacity as elected Office

Date of mailing (day/month/year) 26 September 2001 (26.09.01)	
International application No. PCT/US00/42328	Applicant's or agent's file reference 1032-P02047U
International filing date (day/month/year) 29 November 2000 (29.11.00)	Priority date (day/month/year) 29 November 1999 (29.11.99)
Applicant BOTICH, Michael, J. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
22 June 2001 (22.06.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Anne KARKACHI Telephone No.: (41-22) 338.83.38
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TENT COOPERATION TREATY

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From the INTERNATIONAL BUREAU

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

ELAND, Stephen, H.
Dann Dorfman Herrell And Skillman
Suite 720
1601 Market Street
Philadelphia, PA 19103
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 26 September 2001 (26.09.01)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 1032-P02047U	
International application No. PCT/US00/42328	International filing date (day/month/year) 29 November 2000 (29.11.00)

1. The following indications appeared on record concerning:		
<input type="checkbox"/> the applicant	<input type="checkbox"/> the inventor	<input checked="" type="checkbox"/> the agent
<input type="checkbox"/> the common representative		
Name and Address ELAND, Stephen, H. Dann Dorfman Herrell And Skillman Suite 720 1601 Market Street Philadelphia, PA 19147 United States of America	State of Nationality	State of Residence
	Telephone No. 215-563-4100	
	Facsimile No. 215-563-4044	
	Teleprinter No.	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:		
<input type="checkbox"/> the person	<input type="checkbox"/> the name	<input checked="" type="checkbox"/> the address
<input type="checkbox"/> the nationality		
<input type="checkbox"/> the residence		
Name and Address ELAND, Stephen, H. Dann Dorfman Herrell And Skillman Suite 720 1601 Market Street Philadelphia, PA 19103 United States of America	State of Nationality	State of Residence
	Telephone No. 215-563-4100	
	Facsimile No. 215-563-4044	
	Teleprinter No.	
3. Further observations, if necessary: The new agent's address on the Demand has been considered as a change under Rule 92bis. In case of disagreement, the International Bureau should be notified immediately.		
4. A copy of this notification has been sent to:		
<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned	
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned	
<input checked="" type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:	

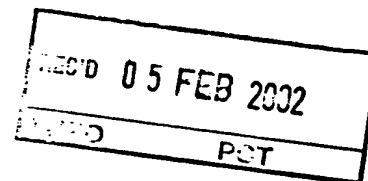
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Anne KARKACHI Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 1032-P02047	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/42328	International filing date (day/month/year) 29 November 2000 (29.11.2000)	Priority date (day/month/year) 29 November 1999 (29.11.1999)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61M 5/32 and US Cl.: 604/195		
Applicant MDC INVESTMENT HOLDINGS, INC.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>0</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none">I <input checked="" type="checkbox"/> Basis of the reportII <input type="checkbox"/> PriorityIII <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicabilityIV <input type="checkbox"/> Lack of unity of inventionV <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statementVI <input type="checkbox"/> Certain documents citedVII <input type="checkbox"/> Certain defects in the international applicationVIII <input type="checkbox"/> Certain observations on the international application		
Date of submission of the demand 22 June 2001 (22.06.2001)	Date of completion of this report 30 November 2001 (30.11.2001)	
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Sharon Kennedy <i>Diane Smith</i> Telephone No. 703-308-4846	

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/42328

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-11 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☒ the claims:
pages 12-19 as originally filed
pages NONE as amended (together with any statement) under Article 19
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☒ the drawings:
pages 1-3 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☒ the sequence listing part of the description:
pages NONE as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/42328

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1-21</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-21</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>1-21</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-21 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a device or method that includes, inter alia, the combination of a syringe barrel and a needle assembly with a needle retainer wherein upon forward displacement of the syringe barrel relative to the needle retainer the needle is released for retraction.

----- NEW CITATIONS -----

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



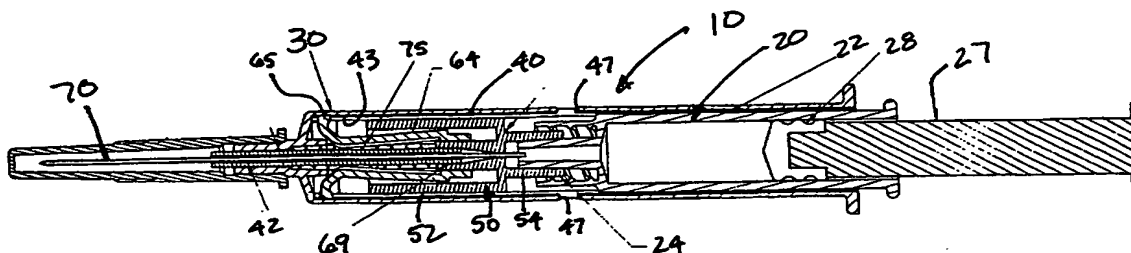
(43) International Publication Date
31 May 2001 (31.05.2001)

PCT

(10) International Publication Number
WO 01/37898 A2

- (51) International Patent Classification⁷: **A61M**
- (21) International Application Number: **PCT/US00/42328**
- (22) International Filing Date:
29 November 2000 (29.11.2000)
- (25) Filing Language: **English**
- (26) Publication Language: **English**
- (30) Priority Data:
60/168,146 29 November 1999 (29.11.1999) **US**
- (71) Applicants (for all designated States except US): **MDC INVESTMENT HOLDINGS, INC.** [US/US]; Delaware Trust Building, Suite 200, 900 Market Street, Wilmington, DE 19801 (US). **BARKER, John** [US/US]; 2333 Aztec Avenue, Venutra, CA 93001 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **BOTICH, Michael, J.** [US/US]; 2330 Eagle Creek Lane, Oxnard, CA 93030 (US). **HALSETH, Thor** [US/US]; 367 Buckboard Circle, Simi Valley, CA 93065 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:**
— Without international search report and to be republished upon receipt of that report.
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **COMBINATION SAFETY NEEDLE ASSEMBLY AND MEDICAL APPARATUS**



(57) Abstract: A method and apparatus are provided for using a medical device (10) comprised of a medical apparatus (20) and a needle assembly (30). The needle assembly includes a needle (70) having a sharpened tip. Preferably, the medical apparatus (20) is a standard apparatus, such as a syringe or phlebotomy device. The medical apparatus (20) includes a connector (24), such as a Luer connector. The needle assembly (30) is configured so that it can be attached to the medical apparatus (20) and the sharpened tip of the needle (70) is automatically shielded after use to prevent inadvertent contact with the contaminated needle.

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(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
31 May 2001 (31.05.2001)

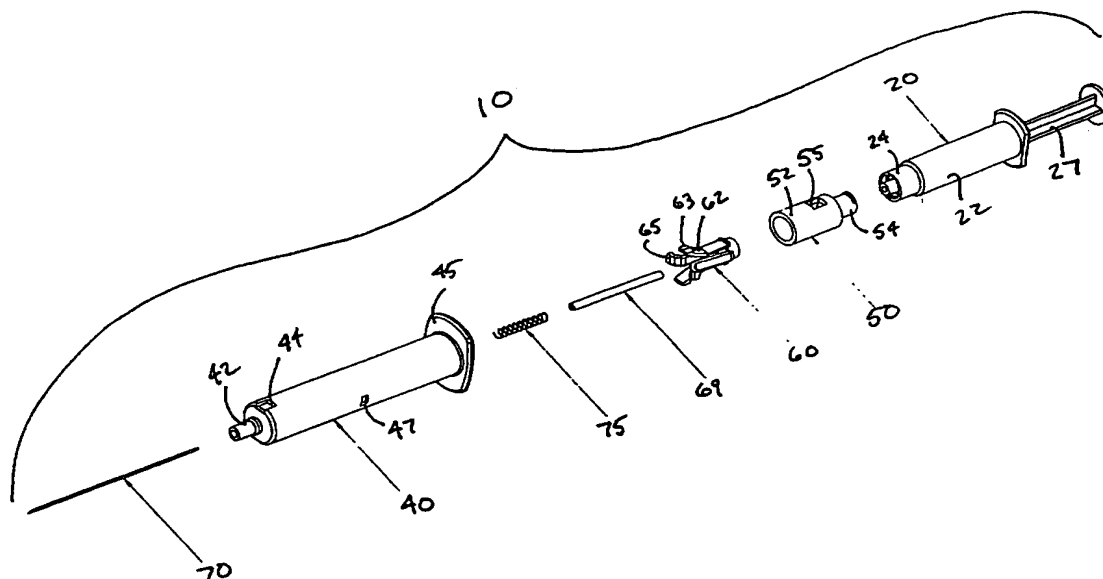
PCT

(10) International Publication Number
WO 01/37898 A3

- (51) International Patent Classification⁷: **A61M 5/32**
- (21) International Application Number: **PCT/US00/42328**
- (22) International Filing Date:
29 November 2000 (29.11.2000)
- (25) Filing Language: **English**
- (26) Publication Language: **English**
- (30) Priority Data:
60/168,146 29 November 1999 (29.11.1999) **US**
- (71) Applicants (for all designated States except US): **MDC INVESTMENT HOLDINGS, INC.** [US/US]; Delaware Trust Building, Suite 200, 900 Market Street, Wilmington, DE 19801 (US). **BARKER, John** [US/US]; 2333 Aztec Avenue, Venutra, CA 93001 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **BOTICH, Michael, J.** [US/US]; 2330 Eagle Creek Lane, Oxnard, CA 93030 (US). **HALSETH, Thor** [US/US]; 367 Buckboard Circle, Simi Valley, CA 93065 (US).
- (74) Agent: **ELAND, Stephen, H.**; Dann Dorfman Herrell And Skillman, Suite 720, 1601 Market Street, Philadelphia, PA 19103 (US).
- (81) Designated States (national): **AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.**
- (84) Designated States (regional): **ARIPO** patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), **Eurasian** patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), **European** patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), **OAPI** patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:
— with international search report
- (88) Date of publication of the international search report:
10 January 2002

[Continued on next page]

(54) Title: **COMBINATION SAFETY NEEDLE ASSEMBLY AND MEDICAL APPARATUS**



(57) Abstract: A method and apparatus are provided for using a medical device (10) comprised of a medical apparatus (20) and a needle assembly (30). The needle assembly includes a needle (70) having a sharpened tip. Preferably, the medical apparatus (20) is a standard apparatus, such as a syringe or phlebotomy device. The medical apparatus (20) includes a connector (24), such as a Luer connector. The needle assembly (30) is configured so that it can be attached to the medical apparatus (20) and the sharpened tip of the needle (70) is automatically shielded after use to prevent inadvertent contact with the contaminated needle.

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/42328

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61M 5/32

US CL : 604/195

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/195, 181,187,192,197,198,171

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,E	US 6,162,197 A (Mohammad) 19 December 2000 (19.12.2000), see entire document.	6
A, P	US 6,017,329 A (Hake) 25 January 2000 (25.01.2000), see entire document.	1-21
A, E	US 6,190,361 B1 (Gettig et al.) 20 February 2001 (20.02.2001), see entire document.	
A	US 5,045,066 A (Scheuble et al.) 3 September 1991 (03.09.1991), see entire document.	1-21

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

06 May 2001 (06.05.2001)

Date of mailing of the international search report

20 JUN 2001

Name and mailing address of the ISA/US

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Box PCT
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